

K 043607

TAB 3

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Official Contact	Zita A. Yurko Manager, Regulatory Affairs/Product Assurance Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 724-387-4120 724-387-4206 (fax) Email: Zita.Yurko@Respironics.com
Classification Reference	21 CFR 868.5905
Product Code	BZD – Non-Continuous ventilator
Common/Usual Name	CPAP System
Proprietary Name	Respironics BiPAP Pro 2 Bi-level System with Bi-Flex
Predicate Device(s)	Respironics BiPAP Pro 2 Bi-level System (K032834) Respironics BiPAP Synchrony Ventilatory Support System (K012323)
Reason for submission	Modified design.

Substantial Equivalence

The modified device has the following similarities to the previously cleared predicate devices:

- Same intended use.
- Same operating principle.
- Same technology.
- Same manufacturing process.

Design verification tests were performed on the Respironics BiPAP Pro 2 Bi-level System as a result of the risk analysis and product requirements. All tests were verified to meet the required acceptance criteria. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the device described in this submission is substantially equivalent to the predicate devices.

The modified device complies with the applicable standards referenced in the Guidance for FDA Reviewers and Industry "Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices," May 1998.

Intended Use

The Respironics BiPAP Pro 2 Bi-level System delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea only. For use in the home or hospital/institutional environment on adult patients.

Device Description

The Respironics BiPAP Pro 2 Bi-level System is a microprocessor controlled blower based bi-level positive pressure system that delivers two different positive pressure levels (IPAP/EPAP). The dual pressure levels provide a more natural means of delivering pressure support therapy to the patient resulting in improved patient comfort. The BiPAP Pro 2 Bi-level System also includes the flex therapy feature cleared in K032834 which provides the patient with additional comfort by easing the transition from the end of inspiration to the beginning of exhalation. This clearance is seeking to extend the Bi-Flex range from 20 to 25 cmH₂O maximum, to provide remote control of the device in a clinical setting and to allow viewing of compliance data by a physician/clinician. Like its predicates, the BiPAP Pro 2 Bi-level System is intended for use with a patient circuit that is used to connect the device to the

patient interface device (mask). A typical patient circuit consists of a six-foot disposable or reusable smooth lumen 22mm tubing, an exhalation device, and a patient interface device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 28 2005

Ms. Zita A. Yurko
Manager, Regulatory Affairs/Product Assurance
Respironics, Incorporated
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K043607
Trade/Device Name: Respironics BiPAP Pro 2 Bi-level System with Bi-Flex
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: December 29, 2004
Received: December 30, 2004

Dear Ms. Yurko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K043607

Device Name: Respironics BiPAP Pro 2 Bi-level System with Bi-Flex

Intended Use/Indications for Use

The Respironics BiPAP Pro 2 Bi-level System with Bi-Flex delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea only.

Environment of Use/Patient Population

For use in the home or hospital/institutional environment on adult patients.


Prescription Use *
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K043607